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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,126	12/12/2001	Connie Sanchez	5432/0J951US0	7268

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805 Third Avenue  
New York, NY 10022

EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/021,126	<b>Applicant(s)</b> SANCHEZ ET AL.	
	<b>Examiner</b> Frederick F. Krass	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.  
4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9 is/are rejected.
- 7) ☒ Claim(s) 10-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12-2-03; 11-21-03</u> . | 6) <input type="checkbox"/> Other: _____  |

### **Status of Case**

Applicant has provided factual evidence of unexpected results which render the previously elected species, panic attacks, allowable as set forth by instant claims 10-14. (Details provided in the discussions to follow). Accordingly, the examiner has extended his search to the next (unelected) claimed species, obsessive-compulsive disorder in claim 9. This species is the subject of the new ground of rejection which follows hereinafter. Because Applicant's response required this shift to a new species, this action is FINAL.

### **Anticipation Rejection (Previous)**

Claims 1-5, 10, 11 and 14 were rejected as being anticipated by Lepola.

This rejection is withdrawn in view of Applicant's argument.

### **Obviousness Rejection (Previous)**

1) Claims 1-5, 10, 11 and 14 were rejected as being obvious over Lepola in view of Boegesoe et al.

2) Claims 12 and 13 were rejected as being obvious over Lepola et al.

These rejections are withdrawn in view of Applicant's arguments.

### **Obviousness Rejection (New)**

Claims 1-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (USP 6,169,105, newly cited) in view of Boegesoe et al.

The primary reference teaches using citalopram, in dosages ranging from 5 to 50 (preferably 10 to 30) mg/day (col. 6, lines 59 and 60), to treat obsessive-compulsive disorder (col. 13, lines 30-36). The prior art differs from the instant claims insofar does not specify any particular stereoisomer of citalopram, i.e. it uses the racemate.

The secondary reference teaches that the activity of citalopram resides entirely within the (+) isomer, i.e. escitalopram (col. 2, lines 38-40). It differs from the instant claims insofar as it specifies the treatment of depression, obesity and alcoholism rather than neurotic disorders.

It would have been obvious to have used the isolated (+) isomer of citalopram, rather than racemic citalopram, to treat obsessive-compulsive disorder as disclosed by the primary reference, because the activity of the racemate (for psychiatric disorders, at least) resides entirely within the (+) isomer as taught by the secondary reference. The motivation to do so would be provided by the expectation of improved therapeutic efficacy and lessened side effects which would be expected upon eliminating the undesirable (-) isomer.

Applicant has provided factual evidence of unexpected results for using escitalopram, as compared to racemic citalopram, in treating panic disorders. (The

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examiner agrees with Applicant's analysis of that evidence substantially as written). No evidence has been provided with respect to obsessive-compulsive disorders, however, as recited in claim 9. Furthermore, the showing is not commensurate in scope with "neurotic disorders" generally as recited by claims 1-5. Results unexpected for one particular acute anxiety state (panic attacks) cannot be reasonably extrapolated to then be expected for "neurotic disorders" in general, an umbrella term inclusive of many different types of disorders having many different etiologies.

#### **Allowable Subject Matter**

Claims 10-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **Action is Final**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;  
Tuesday: 10-6:30PM;  
Wednesday: off;  
Thursday: 10-6:30PM; and  
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Marianne, can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
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A handwritten signature in black ink, appearing to read 'Fred Krass', written over the printed name and title.